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Franklin Lakes, New Jersey 07417
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Attachment 5

K023752

REVISED

Summary of Safety & Effectiveness for the BD Integra™ 1ml Syringe

BD
Indispensable to human [illegible]

FEB 07 2003

1. **BD Contact Person:**
   Pasquale Amato
   Regulatory Affairs Coordinator
   BD Medical Surgical
   BD
   1 Becton Drive MC226
   Franklin Lakes, NJ
   Phone: 201-847-4513
   Fax: 201-847-4855
   E-mail: pasquale_amato@bd.com

2. **Device Name:** BD Integra™ 1ml Syringe

3. **Predicate Devices:** BD Insulin Syringe, Latex Free K980580
   BD Spring Based Syringe K011103
   RTI VanishPoint® Syringe K980069

4. **Product Description/Function:**

   4.1 Description: Single-use syringe with a needle protection system. Needle sizes: 30G-25G, Syringe sizes: 1ml.

5. **Intended uses:** The BD Integra™ Syringe is used for aspiration of fluids from vials and ampoules and a variety of fluid injections below the surface of the skin. It is not intended to be used for phlebotomy. The insulin syringe has scale lines in insulin units and is used for insulin injections. The tuberculin syringe can be used for any of the 3 types of common injections (intra-dermal, intra-muscular or subcutaneous).

   The BD Integra™ 1ml Syringe has a permanently attached needle. The BD Integra™ 1ml Syringe contains a tool used to cut through the hub and stopper allowing the needle to become retracted inside the plunger rod of the syringe after use. After activation the needle is fully contained inside the syringe guarding against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

6. Comparison of Modified & Predicate Devices:

6.1 Descriptive Comparison to a Legally Marketed Device
The BD Integra™ Syringes can be used in the same fashion as standard BD Insulin/Tuberculin syringes. When the BD Integra™ Syringe is in the "ready-to-use" position it provides the same usable injection needle length and same barrel scale markings as a standard insulin / tuberculin syringes.

Comparison has been made to the BD insulin/tuberculin Syringe. The BD Integra™ Syringe is used for aspiration of fluids from vials and ampoules and a variety of fluid injections below the surface of the skin. It is not intended to be used for phlebotomy.

The BD Integra™ Syringe contains a tool used to cut through the stopper and hub allowing the needle to become retracted inside the plunger rod of the syringe after use. After activation the needle is fully contained inside the syringe guarding against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

6.2 Material Changes: There are no significant changes in the materials used for the BD Integra™ Syringe

6.3 Manufacturing Process Changes: The manufacturing processes are being modified to assemble the components associated with the BD Integra™ Syringe.

6.4 Manufacturing Site Changes: No new manufacturing site is being utilized.

6.5 Packaging Component Changes: The package design is being modified to accept the size of the BD Integra™ Syringe.

7. Equivalence determination:

The BD Integra™ Syringe was compared to the predicate devices using the following criteria: shield removal, cannula removal, stopper breakout and sustaining force, hub and stopper leakage, dead space, activation forces, hub/barrel separation forces, cannula containment and splatter. The BD Integra™ Syringes performed in a similar manner to the predicate devices.

A Simulated Use Study was performed on the BD Integra™ 1ml Syringe. The BD Integra™ 1ml Syringe performed equivalently to the BD conventional insulin and tuberculin syringes with respect to the following characteristics:
Overall performance

- Ease of maintaining standard injection technique
- Ability to maintain aseptic technique
- Ability to aspirate medication from a vial
- Ability to read the syringe scale on the barrel
- Ability to passively re-shield and transport
- Ability to easily and safely dispose of the used device in a sharps container
- Perceived safety of the device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 7 2003

BD
Mr. Pasquale Amato
Regulatory Affairs Coordinator
BD Medical Surgical
1 Becton Drive MC226
Franklin Lakes, New Jersey 07417

Re: K023752
Trade/Device Name: BD Integra™ 1 ml Syringe
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG, FMF
Dated: January 16, 2003
Received: January 17, 2003

Dear Ms. Amato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K023752

Device Name: BD Integra™ 1 ml Syringe

Indications for Use:

The BD Integra™ Syringe is used for aspiration of fluids from vials and ampoules and a variety of fluid injections below the surface of the skin. It is not intended to be used for phlebotomy. The insulin syringe has scale lines in insulin units and is used for insulin injections. The tuberculin syringe can be used for any of the 3 types of common injections (intra-dermal, intra-muscular or subcutaneous).

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

Patricia Cucuzza

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: ~~K023752~~
K023752